Appointment

From: Wozniak, Chris [wozniak.chris@epa.gov]
Sent: 2/22/2017 10:03:30 PM
To: Wozniak, Chris [wozniak.chris@epa.gov]; Pease, Anita [Pease.Anita@epa.gov]; Tapken, Wiebke [Tapken.Wiebke@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Kough, John [Kough.John@epa.gov]; Nesci, Kimberly [Nesci.Kimberly@epa.gov]; Leahy, John [Leahy.John@epa.gov]; Borges, Shannon [Borges.Shannon@epa.gov]; Wyatt, TJ [Wyatt.Tj@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Fuentes, Clara [Fuentes.Clara@epa.gov]; Martinez, Jeannette [Martinez.Jeannette@epa.gov]
CC: Odenkirchen, Edward [Odenkirchen.Edward@epa.gov]; Atwood, Donald [Atwood.Donald@epa.gov]; Jones, Arnet [Jones.Arnet@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]

Subject: Oxitec data requirements
Attachments: APPENDIX K - Bioinformatics Final REG 5 Sept 2013-1.pdf; APPENDIX I - Final Report 232SRFR12C1 Poecilia Aedes OX513A 11MAR13EY.pdf; Appendix J Expert opinion 2015 Transgenic protein tTAV - assessment of allergenic risk.pdf; Appendix L SR-00004 ED 1.b signed-tTAV-DsRed-Saliva.pdf; Appendix 2. Critical habitat analysis in Monroe Co.pdf
Location: DCRoomPYS8771/Potomac-Yard-One

Start: 2/28/2017 7:00:00 PM
End: 2/28/2017 8:00:00 PM
Show Time As: Busy

Required Attendees: Wozniak, Chris; Pease, Anita; Tapken, Wiebke; Milewski, Elizabeth; John Kough; Nesci, Kimberly; Leahy, John; Borges, Shannon; Wyatt, TJ; Mendelsohn, Mike; Fuentes, Clara; Martinez, Jeannette
Optional Attendees: Odenkirchen, Edward; Atwood, Donald; Myers, Clayton; Jones, Arnet; Kaul, Monisha

Some relevant background info from Oxitec's submission to FDA. I am waiting for some further input from FDA on penetrance issues and the Toxorhynchites tox study.

Chris

Hold for discussion of data needs re: OX513A

We hope to meet March 6 or 7 with Oxitec to discuss data requirements and a path forward (EUP or Section 18), so hopefully we can pull together a list of what information we feel we need from Oxitec above and beyond what they have provided in the EA as reviewed by FDA, CDC and BPPD. We will need to also think ahead as to what information beyond efficacy data will be important for them to collect in any US field trials. My hope is that we will have list to pass through management by Friday, March 3.

One outstanding question is, will we allow for consideration of efficacy or other data obtained during field trails in the Cayman Islands to this EUP or Section 18 approval?

Thanks

Chris

https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm446529.htm links to FDA's EA and FONSI for OX513A